

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mao et al

Serial No: Not yet assigned

Art Unit: 1714

Filed: Herewith

Examiner: Szekely, P.

For: Biodegradable Polymers Chain-
Extended by Phosphates,
Compositions, Articles and Methods
for Making and Using the Same

Attorney Docket No. GPT-005.03

CERTIFICATE OF EXPRESS MAILING

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William Homan

Hon. Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Prior to substantive examination of the above-referenced patent application, please amend the application as follows:

In the Specification:

Please enter the following amendment in the written description. At page 1, l. 8, please insert the following:

"RELATED APPLICATIONS

This application is a continuation of U.S.S.N. 09/654,326, filed September 1, 2000, which is a continuation of U.S.S.N 09/053,659, now U.S Patent No.6,166,173, filed April 2, 1998 which is a continuation-in-part of U.S.S.N 08/832,217 filed April 3, 1997, all specifications of which are hereby incorporated by reference in their entirety."

In the Claims:

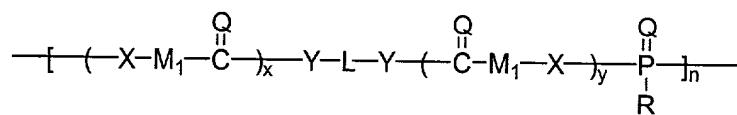
Please cancel claims 1-133 without prejudice and add new claims 134-154:

In the Claims:

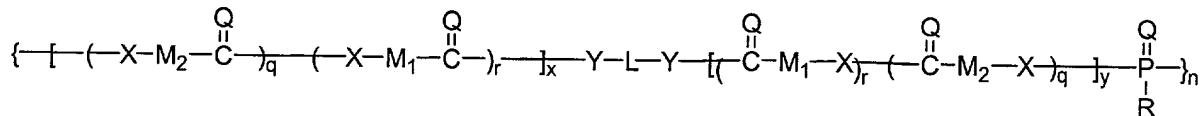
Please cancel claims 1-133 without prejudice and add new claims 134-154:

134. A polymer composition, comprising a polymer comprising the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, wherein R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-, wherein R' is H or alkyl;

Q is O or NR', wherein R' is H or alkyl;

L is a non-interfering substituent;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said polymer is biocompatible before and upon biodegradation.

135. The polymer composition of claim 134, wherein L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group.

136. The polymer composition of claim 135, wherein L is an alicyclic polymer.

137. The polymer composition of claim 136, wherein Q is O.

138. The polymer composition of claim 136, wherein L is selected from a polymer of ethylene glycol or a polymer of propylene glycol.

139. The polymer composition of claim 136 wherein L is a copolymer of ethylene glycol and propylene glycol.

140. The polymer composition of claim 134, wherein said polymer composition is in the form of a block copolymer.

141. The polymer composition of claim 134, wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group or a heterocycloxy group.

142. The polymer composition of claim 135, wherein for each occurrence of M_1 and M_2 in said monomeric unit, M_1 and M_2 is optionally a methyl-substituted -CH- group or a methylene group, Q is O and X is -O-.

143. The polymer composition of claims 134, 140, or 142, further comprising a biologically active substance.

144. The polymer composition of claim 143, wherein said biologically active substance is a neoplastic agent or a local anesthetic.

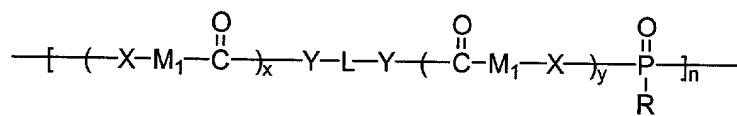
145. The polymer composition of claim 144, wherein said neoplastic agent is paclitaxel.

146. The polymer composition of claim 144, wherein said local anesthetic is lidocaine.

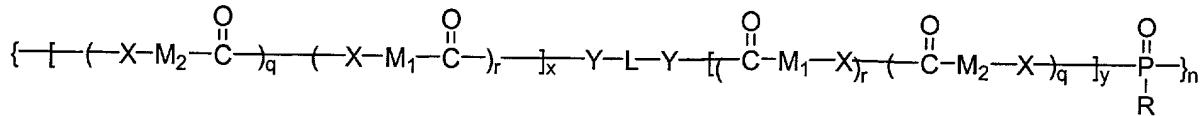
147. A polymer composition comprising:

- (a) at least one biologically active substance, and
- (b) a polymer having the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group, a cyclic aliphatic group, a divalent aryl group, or a polymeric group;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 100:1 and 1:100; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said polymer is biocompatible before and upon biodegradation.

148. The polymer composition of claim 147, wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group or a heterocycloxy group.

149. The polymer composition of claim 148, wherein L is an alicyclic polymer.

150. The polymer composition of 149, wherein: M_1 and M_2 are each an alkylene or alkoxylenne group; L is an alkylene group; X is -O-; and R is an alkoxy group.

151. The polymer composition of claim 147, wherein said polymer composition is in the form of a block copolymer.

152. The polymer composition of claims 147, 150 or 151, wherein said biologically active substance is a therapeutic drug or pro-drug.

153. The polymer composition of claim 152, wherein said biologically active substance is paclitaxel.

154. The polymer composition of claim 152, wherein said biologically active substance is an amide local anesthetic or an ester local anesthetic.

Remarks

Claims 1-133 are pending. Claims 1-133 have been canceled. New claims 134-154 have been added. Support for the newly added claims may be found throughout the specification and in the claims as originally filed.

No new matter has been added.

Cancellation and/or amendment of claims should in no way be construed as an acquiescence, surrender or narrowing of any originally claimed subject matter. The cancellation of the original claims and the substitution of the new claims is being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the option to prosecute further the originally filed claims, or similar ones, in the instant or a subsequent patent application.

Conclusion

If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

Respectfully submitted,

Date: January 15, 2002

Customer No.: 25181

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